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TECHNICAL INFORMATION

EXPOSURE MEASUREMENT
ACTION LEVEL and
OCCUPATIONAL ENVIRONMENTAL
VARIABILITY
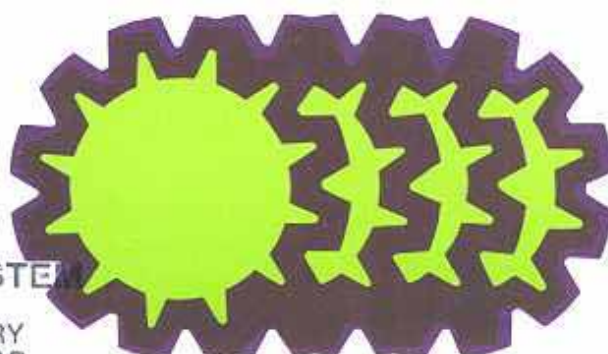
EXPOSURE MEASUREMENT ACTION LEVEL

AND

OCCUPATIONAL ENVIRONMENTAL VARIABILITY

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ACKNOWLEDGMENTS

ABSTRACT

The proposed Occupational Safety and Health Administration health standards define an exposure measurement action level as one half of the permissible exposure limit currently found in 29 CFR 1910.1000, Tables Z-1, Z-2, and Z-3. The action level is the point at which certain provisions of the proposed standards must be initiated, such as periodic employee exposure measurements and training of employees.

The proposed employee exposure monitoring requirements are presented. Comparisions are made between employee exposure monitoring programs and industrial quality control programs. The application of the normal and lognormal frequency distributions to exposure measurements is discussed. Typical occupational variabilities (geometric standard deviations) for particulate, gas, and vapor samples are presented. Statistical theory is given for tolerance limits on time weighted average (TWA) daily exposures and associated employee risk curves.

The action level was set with the view that the employer should minimize the probability that even a very low percentage of actual daily employee exposure (8-hour TWA) averages exceed the standard. Employee risk curves are presented which show the varying probability (risk) that at least 5% of an employee's unmeasured true daily exposure averages will exceed the standard given the fact that the one day's measurement happened to fall below the standard by a specified amount. This calculated risk is almost solely a function of the day to day variability of the true 8-hour TWA exposures. Measurement error makes a very minor contribution to the calculated risk curves.

INTRODUCTION

The objective of this report is to explain the necessity for an employee exposure monitoring action level and its relation to occupational environmental variability. The National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) have had underway since early 1974 a Joint Standards Completion Program (SCP). Federal regulations 29 CFR 1910.1000, Tables Z-1, Z-2, and Z-3 (formerly 1910.93, Tables G-1, G-2, and G-3) established permissible exposure limits for approximately 400 chemical substances. OSHA proposes to amend 29 CFR Part 1910 with standards which, if adopted, will establish requirements for each chemical substance regarding such areas as:

1) measurement of employee exposure,
2) medical surveillance,
3) methods of compliance,
4) handling and use of liquid forms of the substance,
5) employee training,
6) recordkeeping,
7) sanitation and housekeeping.

The proposed standards define the action level as one half of the permissible exposure limit currently found in 29 CFR 1910.1000, Tables Z-1, Z-2, and Z-3. The action level is the point at which certain provisions of the proposed standards must be initiated, such as periodic employee exposure measurements, training of employees, and medical surveillance (if appropriate for the particular substance).

Section 6(b)(7) of the Occupational Safety and Health Act of 1970 (PL-91-596) directs that, where appropriate, occupational health standards shall provide for monitoring or measuring employee exposure at such locations and intervals in such a manner as may be necessary for the protection of employees. NIOSH and OSHA recognized the need to designate an exposure measurement level at which these procedures become appropriate. The function of the action level is to designate this exposure measurement level.

NIOSH and OSHA decided that the action level, which triggers the periodic exposure measurement requirements, be set with the primary consideration of protecting employees from overexposure (exposures exceeding the permissible exposure limit). An exposure monitoring program triggered by an employee exposure measurement exceeding the action level was considered preferable to a monitoring program that includes all employees regardless of their exposures because it was felt that an action level concept would provide the necessary employee protection in conjunction with minimum burden to the employer.

The employer should be confident that no employee is being overexposed. Thus the action level was set with the philosophy that the employer should minimize the probability that even a very low percentage of actual daily employee exposure (8-hour TWA) averages exceed the standard. That is, the employer should monitor employees in such a fashion that he has a high degree of confidence that a very high percentage of actual daily exposures are below the standard.

PROPOSED EMPLOYEE EXPOSURE MONITORING REQUIREMENTS

On 8 May 1975, OSHA published the first six substance health standards as proposed rules in the Federal Register. Below are reprinted the sections (b) and (c) requirements for 2-butanone. These sections will be the same in each SCP substance health standard.

(b)   Exposure determination and measurement.   (1) Each employer who has a place of employment in which 2-butanone is released into the workplace air shall determine if any employee may be exposed to airborne concentration of 2-butanone at or above the action level. The determination shall be made each time there is a change in production process or control measures which could result in an increase in airborne concentration of 2-butanone.

(2)   A written record of the determination shall be made and shall contain at least the following information:

(i)   Any information, observation, or calculations which may indicate employee exposure to 2-butanone;

(ii)   Any measurements of 2-butanone taken;

(iii)   Any employee complaints of symptoms which may be attributable to exposure to 2-butanone; and

(iv)   Date of determination, work being performed at the time, location within the work site, name and social security number of each employee considered.

(3)   If the employer determines that any employee may be exposed to 2-butanone at or above the action level, the exposure of the employee in each work operation who is believed to have the greatest exposure shall be measured.   The exposure measurement shall be representative of the maximum eight-hour time weighted average exposure of the employee.

(4)   If the exposure measurement taken pursuant to paragraph (b)(3) of this section reveals employee exposure to 2-butanone at or above the action level, the employer shall:

(i)   Identify all employees who may be exposed at or above the action level; and

(ii)   Measure the exposure of the employees so identified.

(5)   If an employee exposure measurement reveals that an employee is exposed to 2-butanone at or above the action level, but not above the permissible exposure, the exposure of that employee shall be measured at least every two months.

(6)   If an employee exposure measurement reveals an employee is exposed to 2-butanone above the permissible exposure, the employer shall:

(i)   Measure the exposure of the employee so exposed monthly:

(ii)   Institute control measures as required by paragraph (d) of this section; and

(iii)   Individually notify, in writing, within five days, every employee who is found to be exposed to 2-butanone above the permissible exposure.   The employee shall also be notified of the corrective action being taken to reduce the exposure to at or below the permissible exposure.

(7) If two consecutive employee exposure measurements taken at lease one week apart reveal that the employee is exposed to 2-butanone below the action level, the employer may terminate measurement for the employee.

(8) For purposes of this paragraph employee exposure is that which would occur if the employee were not using a respirator.

(c) Methods of measurement. (1) An employee's exposure shall be obtained by any combination of long term or short term samples which represents the employee's actual exposure averaged over an eight-hour work shift.

(2) The method of measurement shall have an accuracy, to a confidence level of 95 percent, of not less than that given in Table 1.

Table 1

Concentration:	Required accuracy (percent)
Above permissible exposure- - - - - - - - - - - - - - -	± 25
At or below the permissible exposure and above the action level - - - - - - - - - - - - - - - - - - -	± 35
At or below the action level - - - - - - - - - - - - -	± 50

A few terms in the proposed regulations require comment. An employee exposure measurement is a TWA employee exposure as calculated by any combination of long term or short term samples which represents (provides the best estimate of) the employee's actual exposure as averaged over an eight hour work shift. Leidel and Busch (1) have compared the merits of sampling strategies using long term samples and strategies using short term (grab) samples. They also gave recommendations concerning the duration of samples, the number of samples to take, and the period(s) during the work day when the samples should be collected.

The method of measurement refers to the sampling apparatus used to collect the sample along with the chemical analysis procedure used to analyze the sample. Section (c) specifies that the required accuracy of the method be met at a confidence level of 95%. The meaning of this statement is that single samples will lie within the stated required accuracy (percentage limits on each side of the true value) at least 95% of the time.

If normally distributed errors for the method and unbiased methods are assumed, the coefficient of variation (CV or relative standard deviation) can be used as a parameter to judge if the method is accurate enough to meet the standard. The CV in percentage units is defined as 100 times the ratio of the standard deviation of the method, divided by the true concentration being analyzed. The required CV of the method is obtained by dividing the required accuracy by 1.96 (statistical standard normal deviate for 95% two-sided confidence limits, also referred to as Z-value).

Typical required CV's would be:

Concentration	Required Accuracy (plus or minus)	Required CV
Above permissible exposure	25%	Less than 12.8%
At or below the permissible exposure and above the action level	35%	Less than 17.9%
At or below the action level	50%	Less than 25.5%

EMPLOYEE EXPOSURE MONITORING PROGRAMS
AND QUALITY CONTROL PROGRAMS

The technical presentations later in this report are analogous to quality control and assurance programs used widely in industry. The daily exposure TWA average concentrations that an employee is exposed to during his employment is very similar to a product off an assembly line. The assembly line product (and daily exposure average) is subject to:

1) random fluctuations in the process such as between employees or machines performing the same task;
2) gradual trends toward an out-of-tolerance state of the process such as might be caused by machine tool wear; and
3) sudden occurrence of defective parts due to drastic changes in the process.

Below are some similarities between employee exposure monitoring programs and quality control programs.

QUALITY CONTROL PROGRAMS	EMPLOYEE EXPOSURE MONITORING PROGRAMS
1) Detect if a product is out of tolerance or a process is yielding unsatisfactory outputs.	1) Detect if any employee exposures exceed a permissible limit.
2) Institute sampling plans that furnish a maximum amount of protection against sampling errors for a minimum amount of inspection.	2) Institute a monitoring program that needs a minimum amount of sampling for a maximum amount of protection against exposure measurement errors.
3) Institute methods that indicate quickly when something is wrong or about to go wrong with the process before defective work makes its appearance.	3) Institute exposure measurement plans that indicate when the occupational exposures are hazardous or approaching hazardous levels before overexposures occur.
4) Periodically sample from a production process	4) Periodically measure an employee's daily exposure.
5) Limit to a low probability that a bad lot (one containing defectives) will be accepted on the "luck of the the draw" inherent in the sampling process.	5) Limit to a low probability that an employee will be overexposed due to failure to detect days of high exposure because not all days are measured.

6) Detect and attempt to correct sources of process variability that lead to defectives.

6) Detect and try to eliminate sources of high employee exposures.

7) Variations in product quality can be due to;
   a) differences among machines;

   b) differences among workers;

   c) differences in raw materials or component parts;

   d) differences in each of these factors over time.

7) Variability in measurements of employees' daily exposures due to:
   a) differences in work techniques of individual employees (even in the same job category);
   b) differences in the exposure concentrations during a day (reflected in grab samples);
   c) differences in the average daily exposure concentrations between days;
   d) differences due to sampling and analytical determination random errors.
   e) differences in locations of an employee within the plant

NORMAL AND LOGNORMAL FREQUENCY DISTRIBUTIONS

The statistical methods discussed later in this report assume that concentrations in random occupational environmental samples are lognormally and independently distributed both within one eight hour period and over many daily exposure averages. The following discussion of normal and lognormal distributions is reprinted from Leidel and Busch(1) for the convenience of the reader.

Before sample data can be statistically analyzed we must have knowledge of the frequency distribution of the results or some assumptions must be made. Roach (2,3,4) and Kerr(5) have assumed that environmental data is normally distributed. However, it is well established (6,7,8,9) that most community air pollution environmental data is better described by a lognormal distribution. That is, the logarithms (either base e or base 10) of the data are approximately normally distributed. Most importantly, Breslin, et al(10), Sherwood (11,12), Jones and Brief (13), Gale (14,15), Coenen (16,17), Hounam (18), and Juda and Budzinski(19,20) have shown that occupational environmental data from both open air and confined work spaces for both short (seconds) and long (days) time periods are lognormally distributed.

What are the differences between normally and lognormally distributed data? First, it should be remembered that a "normal" distribution is completely determined by two parameters: 1) the arithmetic mean (μ), and 2) the standard deviation (σ) of the distribution. On the other hand, a "lognormal" distribution is completely determined by 1) the median or geometric mean (GM), and 2) the geometric standard deviation (GSD). For lognormally distributed data, a logarithmic transformation of the original data is normally distributed. The GM and GSD of the lognormal distribution are the antilogs of the mean and standard deviation of the logarithmic transformation. Normally distributed data has a symmetrical distribution curve while lognormally distributed environmental data is generally positively skewed (long "tail" to the right indicating a larger probability of very large concentrations than for normally distributed data). Figure 1 compares a lognormal distribution to a normal distribution that has the same arithmetic mean (μ) and standard deviation (σ). The conditions conductive to (but not all necessary for) the occurrence of lognormal distributions are found in occupational environmental data. These conditions are (16):

1) *the concentrations cover a wide range of values, often several orders of magnitude,*
2) *the concentrations lie close to a physical limit (zero concentration),*
3) *the variability of the measured concentration is of the order of the size of the measured concentration, and*
4) *there is a finite probability of very large values (or data "spikes") occurring.*

The variability of occupational environmental data (differences between repeated measurements at the same site) can usually be broken into three major components: 1) random errors of the sampling method, 2) random errors of the analytical method, and 3) variability of the environment with time. The first two components of the variability are usually known in advance and are approximately normally distributed. However the environmental fluctuations of a contaminant in a plant usually greatly exceed the variability of known instruments (often by factors of 10 or 20). The above components of variability were discussed in an article by LeClare, et al. (21).

When several samples are taken in a plant to determine the average concentration of the contaminant and estimate the average exposure of an employee then the lognormal distribution should be assumed. However, the normal distribution may be used in the special cases of 1) taking a sample to check compliance with a ceiling standard, and 2) when a sample (or samples) is taken for the entire time period for which the standard is defined (be it 15 minutes or eight hours). In these cases the entire time interval of interest is represented in the sample and only sampling and analytical errors are present.

The relative variability of a normal distribution (such as the random errors of the sampling and analytical procedures) is commonly measured by the coefficient of variation (CV). The CV is also known as the relative standard deviation. The CV is a useful index of dispersion in that limits consisting of the true mean of a set of data plus or minus twice the CV will contain about 95% of the data measurements. Thus if an analytical procedure with a CV of 10% is used to repeatedly measure some nonvarying physical property (as the concentration of a chemical in a beaker of solution) then about 95% of the measurements will fall within plus or minus 20% (2 times the CV) of the true concentration.

Unfortunately the property we are trying to measure, the employee's exposure concentration, is not a fixed nonvarying physical property. The exposure concentrations are fluctuating in a lognormal manner. First, the exposure concentrations are fluctuating over the eight hour period of the TWA exposure measurement. Breathing zone grab samples (samples of less than about 30 minutes duration, typically only a few minutes) tend to reflect this intraday environmental variability so that grab sample results have relatively high variability. However, intraday variability in the sample results can be eliminated from measurement variability by going to a full period sampling strategy as discussed by Leidel and Busch(1). The day to day (interday) variability of the of the true 8-hour TWA exposures is also lognormally distributed. It is this interday variability which creates a need for an action level where only one day's exposure measurement is used to draw conclusions regarding compliance on unmeasured days.

The parameter often used to express either the intraday or interday environmental variability is the geometric standard deviation (GSD). A GSD of 1.0 represents absolutely no variability in the environment. GSDs of 2.0 and above represent relatively high variability. The section following discusses typical GSDs found in occupational environments.

Hald(22) states that the shape of lognormal distributions with low variabilities, such as those with GSDs less than about 1.4, roughly approximate normal distribution shapes. For this range of GSDs there is a rough equivalnece between the GSD and CV as follows:

GSD	Approximate CV
1.40	35%
1.30	27%
1.20	18%
1.10	9.6%
1.05	4.9%

OCCUPATIONAL ENVIRONMENTAL VARIABILITY

In order to use the statistical model in the next section, one must have estimates of the typical temporal variabilities found in the occupational environment. As discussed previously, the parameter used as a measure of variability is the geometric standard deviation (GSD).

Ayer and Burg(23) estimated and compiled over 100 GSD's from the literature and other data available to the authors. A histogram of the Ayer and Burg data is shown in Figure 2. The median category for the Ayer and Burg GSD's is 1.60 to 1.69. That is, about one half of the 105 GSD's lie below 1.65 and one half exceed 1.65. Also, less than 7% of their GSD's lie below 1.20.

The Ayer and Burg data is almost exclusively particulate samples. That is, the samples were collected for materials such as silica dust, lead dust, cotton dust, asbestos dust, and radioactive particles. Since there might be a difference in GSD's between particulate atmospheres and gas/vapor atmospheres a data analysis of gas and vapor data was conducted. The Hazard Evaluation Services Branch of the NIOSH, Division of Technical Services has conducted over 200 Health Hazard Evaluations under the provisions of 42 CFR Part 85. These investigations are conducted by trained NIOSH industrial hygienists using the latest sampling methods. The samples are generally analyzed by the NIOSH Physical and Chemical Analysis Branch which operates under a stringent analytical quality control program. The file of 204 reports was searched for appropriate data for analysis using the following guidelines:

a) select only gas and vapor samples,
b) select only breathing zone samples (exclude general air samples),
c) select sample groups where exposure levels were generally greater than 25% of the standards,
d) select sample groups with three or more samples.

The results are shown in Table 2. There were 59 GSD's calculated and their distribution is shown in the histogram of Figure 3. The median category for the gas and vapor data is 1.50 to 1.59. That is, about one half the GSD's lie below 1.55 and one half exceed 1.55. This is lower than the 1.65 median of the Ayer and Burg(22) particulate data. However, conclusions regarding significant differences between the distributions should not be made since the techniques of data selection, group sizes, and GSD calculation differ between the particulate GSD's and gas and vapor GSDs. Many of the gas and vapor GSDs group sizes had sample sizes of three.

The purpose of presenting the preceding GSDs was to show the range of GSDs found in particulate, gas, and vapor samples. Three basic types of variability were tabulated:

1) interoperator (between workers in the same job category),
2) intraday (between samples taken on one eight-hour shift on one worker),
3) interday (between daily exposure averages (8-hour TWA) on the same worker).

Table 2

Industry (operation)	Job	Chemical	n	GSD	Variability of	Reference
filling aerosol cans with solvent	filler ops	perchloroethylene	9	1.75	operators	71-25-20
		xylene	9	1.92	operators	71-25-20
		diacetone alcohol	9	1.41	operators	71-25-20
	valve droppers	perochloroethylene	12	1.99	operators	71-25-20
		xylene	12	1.81	operators	71-25-20
		diacetone alcohol	12	2.43	operators	71-25-20
	gasser ops	perchloroethylene	9	2.20	operators	71-25-20
		xylene	9	2.14	operators	71-25-20
		diacetone alcohol	9	2.20	operators	71-25-20
plastics fabrication and finishing	mix room opr.	styrene	4	2.04	intraday	72-68-25
	press opr.	strene	3	1.52	intraday	72-68-25
	preform opr.	styrene	4	1.37	intraday	72-68-25
metal fabrication with vapor degreasing	degreaser opr.	trichloroethylene	5	1.27	intraday	72-84-31
	degreaser opr. leadman, small	trichloroethylene	5	1.35	intraday	72-84-31
	compressor assembler	trichloroethylene	3	1.28	intraday	72-84-31
	compressor assembler	trichloroethylene	4	1.15	intraday	72-84-31
metal finishing with degreasing	Visi-trol oprs.	1,1,1-trichloroethane	5	1.31	operators	72-35-34
	Vis-trol oprs.	tetrachloroethylene	5	1.27	operators	72-35-34
contact cement gluing	gluing opr.	toluene	7	1.45	interday	72-48-35
	gluing opr.	toluene	7	1.45	intraday	72-48-35
	drying opr.	toluene	8	3.11	intraday	72-48-35
	drying opr.	toluene	8	2.76	intraday	72-48-35

(Con't)

Industry (operation)	Job	Chemical	n	GSD	Variability of	Reference
printed circuit board fabrication	sprayer	trichloroethylene	3	1.31	interday	72-74-51
	sprayer	trichloroethylene	3	1.53	intraday	72-74-51
	washer	trichloroethylene	3	1.21	intraday	72-74-51
	washer	trichloroethylene	3	1.57	interday	72-74-51
	washer	trichloroethylene	3	1.12	intraday	72-74-51
	tester	trichloroethylene	3	1.22	interday	72-74-51
	tester	trichloroethylene	3	1.09	intraday	72-74-51
	tester	trichloroethylene	3	2.30	interday	72-74-51
	tester	trichloroethylene	3	1.06	intraday	72-74-51
	solderer	trichloroethylene	3	1.49	intraday	72-74-51
	solderer	trichloroethylene	3	1.65	interday	72-74-51
	cleaner	trichloroethylene	3	1.90	intraday	72-74-51
fluorescent light ballast mfg.	cleaner	pet.distillate(naphtha)	5	1.41	operators	72-107-88
	cleaner	pet.distillate(naphtha)	9	1.49	operators	72-107-88
	loader	pet.distillate(naphtha)	3	1.72	operators	72-107-88
	audit tester	pet.distillate(naphtha)	3	1.18	operators	72-107-88
fibrous glass layup and fabrication	gunner	styrene	3	1.03	intraday	73-103-128
	gunner	styrene	3	1.29	intraday	73-103-128
	roller	styrene	6	1.12	operator	73-103-128
	roller	styrene	3	1.14	operator	73-103-128
aerosol mounting cups	gasket mach.opr.	toluene	8	1.90	operators	73-176-163
vending mach.mfg.	degreaser	trichloroethylene	4	2.49	operators	74-208-164
cellophane sheet mfg.	coating opr.	tetrahydrofuran	7	1.66	operators	74-4-175
fibrous glass container mfg.	60" mold opr.	styrene	4	1.84	operators	73-126-186
	spin cast opr.	styrene	5	1.17	operators	73-126-186
	fibrous glass chopper	styrene	7	1.45	operators	73-126-186

(Con't)

Industry (operation)	Job	Chemical	n	GSD	Variability of	Reference
label varnishing	operator	pet. naphtha	9	1.71	intraday	74-113-192
	operator	pet. naphtha	9	2.30	intraday	74-113-192
baseball bat mfg.	belt rubber	pet. naphtha	4	1.13	operators	74-121-203
plastic sheet mfg.	mixers	methyl methacrylate	9	1.48	operators	KK
	mold fillers	methyl methacrylate	12	1.61	operators	KK
	mix men	methyl methacrylate	6	1.82	operators	KK
	mix men	methyl methacrylate	15	1.87	operators	KK
	mold fillers	methyl methacrylate	40	1.61	operators	KK
	mold fillers helpers	methyl methacrylate	7	1.90	operators	KK
	mix men	methyl methacrylate	22	1.82	operators	KK
	headmen	methyl methacrylate	4	2.22	operators	KK

NOTE: Reference numbers refer to Health Hazard Evaluation Report numbers issued by the Hazard Evaluation Services Branch of the NIOSH Division of Technical Services. The reference "KK" refers to data provided by Ken Kroneveter of the Industrial Hygiene Services Branch, Division of Technical Services, NIOSH.

Statistical Theory for Tolerance Limits on Time Weighted Average (TWA) Daily Exposures and Associated Employee Risk Curves

In an earlier section of this report entitled Normal and Lognormal Frequency Distributions, we have documented the basis for statistical assumptions regarding the distributional forms of component errors which make up the total error in an environmental measurement of employee exposure. In this section, these assumptions are given in mathematical form and statistical formulae are derived which will be useful for evaluating the risk that excessive TWA employee exposures have occurred or will occur on other work days as a function of today's measured exposure level. Such risk curves obviously relate to the validity of the action level concept. Specifically, we will now introduce the following model for a kth replicate concentration measurement (x_{ijk}) made at a jth randomly selected sampling period of the work day on an ith randomly selected work day.

$$x_{ijk} = \mu \, d_i \, e_{(i)j} + a_{(ij)k} \, , \qquad \text{where:}$$

μ = the true long term mean of 8-hour TWA's. The process is assumed to be stable so that exposure levels exhibit no trends or cycles.

d_i = factor for the ith day, $i = 1, 2, \ldots$. The true mean for the ith day is denoted by $\mu_i = \mu \, d_i$.

$e_{(i)j}$ = factor for the jth sampling period within the ith day, $j = 1, 2, \ldots, q$. The true mean for the jth period of the ith day is given by $\mu_{ij} = \mu \, d_i \, e_{(i)j}$.

$a_{(ij)k}$ = differential net error of sampling and analysis for the kth sample of the jth period on the ith day, k = 1, 2, . . . , n. (Each sample is assumed to be analyzed only once so that a single term in the model can be used for the net sampling and analysis error.)

The distribution assumptions are given below.

$$a_{(ij)k} \sim N(0, CV_A^2 \mu_{ij}^2)$$ where μ_{ij} is the true concentration for the jth period of the ith day and CV_A is the coefficient of variation for analytical and sampling errors, i.e.

$$\mu_{ij} = \mathop{E}_{k} (x_{ijk}) = \mu \, d_i \, e_{(i)j} \, ,$$

$$CV_A = \sigma_{ij}/\mu_{ij} \quad , \quad \text{and}$$

$$\sigma_{ij}^2 = \mathop{E}_{k} ((x_{ijk} - \mu_{ij})^2) = \mathop{V}_{k} (a_{(ij)k})$$

The notation $\mathop{E}_{k}(\ )$ is utilized to indicate that the operator E (designating the taking of an expected (mean) value) is applied to the population of all values indexed by k of the function of random variables written within the parentheses. The notation $\mathop{V}_{k}(\ )$ is used to denote the corresponding variance.

The notation $x \sim N(\mu,\sigma^2)$ means that the random variable x is distributed normally with mean μ and variance σ^2 (standard deviation = square root of second term within parentheses).

The multiplicative terms of the model, d_i and $e_{(i)j}$, represent day-to-day and within-day variations, respectively. They are assumed to be independently log-normally distributed as indicated below.

$$\ln d_i \sim N(-(1/2)\sigma_D^2, \sigma_D^2)$$

$$\ln e_{(i)j} \sim N(-(1/2)\sigma_E^2, \sigma_E^2)$$

In the case of $\ln d_i$, the mean and variance are computed over a population of work days; whereas for $\ln e_{(i)j}$, the mean and variance are computed over times of day within the ith work day. (Note. The means of these random multiplicative effects are not zero on the log scale. Rather, their ln means are defined in such a way that the corresponding arithmetic means are unity, i.e. $\underset{i}{E}(d_i) = 1$ and $\underset{j}{E}(e_{(i)j}) = 1$. It follows that $e^{(1/2)\sigma_E^2}$ is the ratio of the arithmetic mean to the geometric mean for the ith day. The corresponding ratio between the two types of long-term means is equal to $e^{(1/2)(\sigma_D^2 + \sigma_E^2)}$.)

Thus, our model for a concentration measurement, x_{ijk}, is a mixture of log-normally distributed inter-day and intra-day variations in conjunction with additive normally distributed errors of sampling and assay. (This model was developed for the case of a single assay of each sample.)

Since a model consisting of such a mixture of normal and log-normal terms is very difficult to treat mathematically, a simplifying approximation will be introduced at this time. We will approximate the normal distribution of

additive errors $a_{(ij)k}$ by means of a log-normal distribution of corresponding multiplicative errors $v_{(ij)k}$. First rewrite the model in the form:

$$x_{ijk} = \mu\, d_i\, e_{(i)j}\, v_{(ij)k} \; , \quad \text{where}$$

$$v_{(ij)k} = 1 + (a_{(ij)k} / \mu\, d_i\, e_{(i)j}) \; .$$

It could easily be shown that $v_{(ij)k}$, the standardized multiplicative transformation of the additive error $a_{(ij)k}$, is also normally distributed and has mean 1 and standard deviation equal to the coefficient of variation of the additive error. That is,

$$v_{(ij)k} \sim N(1, CV_A^2), \quad \text{where}$$

$$\mathop{E}_k(v_{(ij)k}) = 1 \quad \text{and} \quad \mathop{V}_k(v_{(ij)k}) = CV_A^2 \; .$$

As an approximation, we will treat this normal distribution of v's as if it were instead a log-normal distribution with the same mean and variance. Under this approximation, the log transformation of v would be treated as if it were normally distributed with mean and variance given by:

$$\mathop{E}_k(\ln v_{(ij)k}) = (-1/2)\ln (1+CV_A^2)$$

$$\text{and} \quad \mathop{V}_k(\ln v_{(ij)k}) = \ln (1+CV_A^2)$$

These formulas can be derived from general formulae given in Aitchison and Brown (24).

To summarize, we have introduced a log-normal approximation to the normal distribution of v, so that hereafter we will assume:

$$\ln v_{(ij)k} \sim N(-1/2 \ln (1+CV_A^2), \ln (1+CV_A^2)).$$

Hald (22) indicates that this should be an excellent approximation - certainly good enough for use in making calculations such as ours - so long as $CV_A < 1/3$ (which will almost certainly be the case).

Under the above approximation, the full concentration model can now be written in terms of its logarithmic transform:

$$\ln x_{ijk} = \ln \mu + \ln d_i + \ln e_{(i)j} + \ln v_{(ij)k} .$$

Since the terms on the right are a linear combination of independently normally distributed variables, it follows that the sum is also normally distributed as follows:

$$\ln x_{ijk} \sim N(\ln \mu - (1/2)(\sigma_D^2 + \sigma_E^2 + \ln(1+CV_A^2)), \ln(1+CV_A^2) + \sigma_D^2 + \sigma_E^2) .$$

Introducing the symbol S for the Federal Health Standard (Std), the model can also be written in terms of the standardized ratio of the measurement divided by the standard.

$$\ln(x_{ijk}/S) \sim N(\ln(\mu/S) - (1/2)(\sigma_D^2 + \sigma_E^2 + \ln(1+CV_A^2)), \ \ln(1+CV_A^2) + \sigma_D^2 + \sigma_E^2) \ ,$$

where: $\underset{i}{V}(\ln d_i) = \sigma_D^2 = (\ln GSD_D)^2$, and

$$\underset{j}{V}(\ln e_{(i)j}) = \sigma_E^2 = (\ln GSD_E)^2 \ .$$

The true TWA average exposure concentration for the ith day was defined to be:

$$\mu_i = \underset{j,k}{E} (x_{ijk}) = \mu \, d_i \ , \quad \text{so that}$$

$$\ln \mu_i = \ln \mu + \ln d_i \quad .$$

Since $\ln \mu_i$ is simply a constant ($\ln \mu$) added to a normally distributed random variable, it is easy to write the $(1 - \Theta)$-level fractile of the distribution of values of $\ln (\mu_i/S)$. We have

$$\ln(\mu_i/S) \sim N(\ln(\mu/S) - (1/2)\sigma_D^2, \ \sigma_D^2) \quad \text{so that the required}$$

fractile is defined by the following probability expression:

$$P(\ln(\mu_i/S) > \ln(\mu/S) - (1/2)\sigma_D^2 + Z_{1-\Theta} \ \sigma_D) = \Theta \quad ,$$

where $Z_{1-\Theta}$ is the $1-\Theta$ fractile of the standard normal distribution. For example, $Z_{.95} = 1.645$ for $\Theta = .05$.

Now let $d_{i'}$ be the day-effect factor for a randomly selected work day other than that whose TWA measurement we have at hand, i.e. let $i' \neq i$. The following distribution will also be useful to us further below.

$$\ln(x_{ijk}/d_{i'}) \sim N(\ln \mu - (1/2)(\sigma_E^2 + \ln(1+CV_A^2)), \ln(1+CV_A^2) + 2\sigma_D^2 + \sigma_E^2).$$

Based on the last-written distribution, we can make another probability statement involving a $(1-\gamma)$ fractile of the distribution of $\ln(x_{ijk}/d_{i'})$, namely

$$P(\ln x_{ijk} - \ln d_{i'} < \ln \mu - (1/2)(\sigma_E^2 + \ln(1+CV_A^2))$$

$$- Z_{1-\gamma} \sqrt{\ln(1+CV_A^2 + 2\sigma_D^2 + \sigma_E^2}\,) = \gamma .$$

Now rearrange terms of the inequality in order to obtain a $(1-\gamma)$ level fractile limit for the logarithms of the true mean of the i'th day.

$$P_F (\ln \mu + \ln d_{i'} > \ln x_{ijk} + (1/2)(\sigma_E^2 + \ln(1+CV_A^2))$$

$$+ Z_{1-\gamma} \sqrt{\ln(1+CV_A^2) + 2\sigma_D^2 + \sigma_E^2}\,) = \gamma .$$

In this latter context, the quantity γ is no longer a true probability and is called instead a confidence coefficient. It is denoted by P_F since such a probability (representing degree of belief) can also be derived through the theory of so-called fiducial probability distributions.

Remembering that $\ln \mu_{i\prime} = \ln \mu + \ln d_{i\prime}$, we can then write:

$$P_F(\ln(\mu_{i\prime}/S) \; \gtrdot \; \ln(x_{ijk}/S) + (1/2)(\sigma_E^2 + \ln(1+CV_A^2))$$

$$+ \; Z_{1-\gamma}\sqrt{\ln(1+CV_A^2) + 2\sigma_D^2 + \sigma_E^2}\;) \; = \; \gamma.$$

The above inequality whose confidence coefficient is given by γ is similar to another whose probability was derived earlier and will be rewritten here:

$$P(\ln(\mu_i/S) \; > \; \ln(\mu/S) - \sigma_D^2/2 + Z_{1-\Theta}\,\sigma_D) \; = \; \Theta$$

Both the confidence coefficient γ and the probability Θ express, in different ways, degrees of belief that a future true TWA daily mean will exceed a limiting value. The limit given in the probability statement Θ is a true $1-\Theta$ level fractile but it cannot be known because it is a function of the unknown true long-term mean. On the other hand, the limit given with confidence coefficient γ is an estimated fractile because it is a function of the random measurement x_{ijk} . The latter limit (using P_F and γ) will be referred to as an upper tolerance limit (UTL). We will now attempt to choose the standard normal deviate $Z_{1-\gamma}$ in the expression for the random UTL so that we can have a desired probability, P say, that the random upper tolerance limit will be less than the true (fixed) fractile limit. Such a value of P will also be equal to the probability that γ exceeds Θ or, equivalently, P can be defined as follows:

   P = P(at least 100 Θ% of true daily means will exceed the random

      upper tolerance limit (UTL) calculated from x_{ijk}).

Our purpose in developing this theory, of course, is to be able to evaluate an employee's risk of being exposed above the standard as a function of: 1) the current day's exposure measurement, and 2) the magnitudes of various types of temporal variation in the true exposure level and of measurement errors. The above definition of P can be adapted to this purpose by setting UTL = S. The resultant P has the following meaning:

$$P = P(100 \; \theta\% \text{ or more of daily means exceed } S).$$

The steps required to derive a formula for P are given below.

$$P = P(\gamma > \theta)$$

$$= P(\ln(x_{ijk}/S) + (1/2)(\sigma_E^2 + \ln(1+CV_A^2))$$

$$+ Z_{1-\gamma}\sqrt{\ln(1+CV_A^2) + 2\sigma_D^2 + \sigma_E^2} < \ln(\mu/S) - \sigma_D^2/2 + Z_{1-\theta}\,\sigma_D)$$

$$= P(\ln(x_{ijk}/\mu) \quad Z_{1-\theta}\,\sigma_D - (1/2)(\sigma_D^2 + \sigma_E^2 + \ln(1+CV_A^2))$$

$$- Z_{1-\gamma}\sqrt{\ln(1+CV_A^2) + 2\sigma_D^2 + \sigma_E^2}\;) \quad .$$

Since $\ln(x/\mu)$ is normally distributed, P can be found from a table of the standardized normal distribution, where

$$P = \int_{-\infty}^{Z_P} (1/\sqrt{2\pi})e^{-(1/2)t^2} \, dt, \quad \text{and}$$

$$Z_P = \left(Z_{1-\Theta}\,\sigma_D - Z_{1-\gamma}\sqrt{\ln(1+CV_A^2) + 2\sigma_D^2 + \sigma_E^2}\,\right) / \sqrt{\ln(1+CV_A^2) + \sigma_D^2 + \sigma_E^2} \ .$$

Solving for $Z_{1-\gamma}$ yields the solution:

$$Z_{1-\gamma} = \left(Z_{1-\Theta}\,\sigma_D - Z_P\sqrt{\ln(1+CV_A^2) + \sigma_D^2 + \sigma_E^2}\,\right) / \sqrt{\ln(1+CV_A^2) + 2\sigma_D^2 + \sigma_E^2}$$

which is the required factor for calculating tolerance limits which are exceeded by 100 Θ% or more of true daily means 100 P% of the time.

Now equate the $(1-\gamma)$-level upper tolerance limit for the true daily mean to S; i.e. set UTL, the upper tolerance limit for μ_i/S, equal to unity.

$$\ln(\text{UTL}) = \ln(1) = 0 = \ln(x_{ijk}/S) + (1/2)(\sigma_E^2 + \ln(1+CV_A^2))$$

$$+ \ Z_{1-\gamma}\sqrt{\ln(1+CV_A^2) + 2\sigma_D^2 + \sigma_E^2} \quad .$$

where $Z_{1-\gamma}$ is given by the previous formula.

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Solve the last two equations simultaneously for Z_p. The solution is:

$$Z_p = (\ln(x_{ijk}/S) + Z_{1-\Theta}\,\sigma_D + (1/2)\ln(1+CV_A^2) + (1/2)\sigma_E^2) \,/\, \sqrt{\ln(1+CV_A^2) + \sigma_D^2 + \sigma_E^2} \quad .$$

In order to simplify a graphical presentation of this result, we will assume that an intermediate level, $CV_A = 0.10$, for the coefficient of variation of sampling and analytical error exists and that a TWA concentration measurement $\overline{x}_{i.k}$ has been made based on a sample taken over the full period of the standard so that $\sigma_E^2 = 0$. Then Z_p reduces to

$$Z_p = \ln(\overline{x}_{i.k}/S) + Z_{1-\Theta}\,\sigma_D + (1/2)\ln(1.01)) \,/\, \sqrt{\ln(1.01) + \sigma_D^2} \quad .$$

Corresponding values of P = P(100 Θ% or more of daily TWA exposures exceed S) were obtained by referring Z_p values to tables of the normal distribution. The P values were then plotted against x/S (i.e. $\overline{x}_{i.k}$) as shown in Figure (4) for $\Theta = .05$. Different curves are shown for several values of GSD_D - for each of these curves $\sigma_E^2 = 0$ and $CV_A = 0.1$ were used in conjunction with GSD_D to calculate the total error which determines the risk P. However, the curves are identified only by the chosen GSD_D values for "pure" day-to-day variability since the other components of error are the same for all curves.

DISCUSSION AND RECOMMENDATIONS

The primary consideration of the action level is to protect employees from overexposures (exposures exceeding the permissible exposure limit). The employer should minimize the possibility for each employee that even a low percentage of the true daily exposure (8-hour TWA) averages exceed the standard. Stated differently, the employer should monitor each employee in such a fashion that there is a high degree of confidence that each employee has a high percentage of actual daily exposures below the standard.

The proposed rules require in effect that decisions concerning an employee's exposure status be made on the basis of one days' exposure measurement out of many possible exposure days. If the employee's exposure status is at or above the action level, but not above the permissible exposure standard, an exposure measurement must be made for that employee at least every two months (about every 42 working days).

An exposure measurement on one day is an estimate of the true daily exposure average for that day. The true daily exposure for one day in turn was chosen from a lognormal distribution of other true daily exposures covering the period selected. The problem can now be formulated into a statistical one. The statistical methods of the preceding section were developed and Figure 4 is the result of calculations using these methods.

Figure 4 shows the effect the day to day variability in true daily exposure averages (and a sampling/analytical CV of 10%) has on the confidence coefficient (probability) that a least 5% (or greater) of actual daily exposure (8-hour TWA) averages exceed if the one days' exposure measurement (8-hour TWA) is at or below the standard. Basically, Figure 4 shows the probability that at least 5% of an employee's unmeasured true daily exposure averages will exceed the standard given the fact that one days' measurement happened to fall below the standard. Declaring an employee as "safe" and never sampling again because one days' exposure measurement fell below the standard would be analogous to accepting a factory's entire production on the basis of only one tested product.

Figure 4 is the primary technical basis for the recommendation of an action level of one half (0.5) the standard. It is felt that the employer should try to limit to 5% probability, that no more than 5% (or greater) of an employee's actual (true) daily exposure averages exceed the standard. Figure 4 shows that the action level for this low 0.05 probability (confidence of 95%) is a function of the interday variability of the true daily exposures (combined with an assumed sampling/analytical CV of 10%). Higher GSDs require lower fractional action levels. A GSD of 2.0 requires an action level as low as 0.115 of the standard!

Figure 4 was prepared using an assumed 10% sampling and analytical coefficient of variation (CV). This corresponds to a measurement method with about a 20% accuracy at a confidence level of 95%. However, the curves are labeled for "pure" interday variability. It is very important to realize that the measurement method error makes a very minor contribution to the calculated employee risk of having a given percentage of the true daily averages exceed the standard. The calculated risk is almost solely a function of the day to day variability.

A variable action level for each employee based on the day to day variability of each employee's daily exposure averages was considered. However, a relatively large number of samples would have to be taken in order to determine each employee's variability to any degree of accuracy. This was considered to be an unreasonable burden on the employer. Instead it is felt the best answer is to choose an action level based on typical variabilities found in industry.

Figure 4 shows that employees with day to day daily exposure average variabilities less than about 1.22 (combined with a sampling/analytical CV of 10%) have less than 5% probability of having 5% of their true daily exposures exceed the standard on unmeasured days. It is felt that very few interday variabilities are less than 1.22. Note that if one measured daily exposure average is at one half the standard then the following probabilities exist that at least 5% of the unmeasured true daily averages exceed the standard:

Interday Variability	Probability
GSD = 1.3	17%
= 1.5	47%
= 2.0	72%
= 3.0	83%

Finally, it should be noted that the above considerations are very conservative regarding the stability of the distribution of true daily exposures the employee is confronted with. The only variabilities considered are random ones. That is, there is the possibility of unpredictable upward trends or sudden increases in the distribution of daily exposures due to changes in the employee's environment such as:

1) closing plant doors and windows in cold seasons,

2) decreases in efficiency or failure of engineering control measures such as ventilation systems,

3) changes in the production process leading to increased exposures.

Nomenclature

CV	Coefficient of variation, a measure of relative dispersion (variability) of a normal distribution. Also known as the relative standard deviation and is defined as (σ/μ)
GSD	Geometric standard deviation, a measure of relative dispersion (variability) of a lognormal distribution. Equal to e^{s_ℓ}
s	Estimated standard deviation calculated from a sample of original data.
s_ℓ	Estimated standard deviation of ln (base e logarithms) calculated from a sample of original data.
std	Occupational health employee exposure standard such as the Federal standards 29 CFR 1910.1000 (formerly 29 CFR 1910.93). Also referred to as the permissible exposure.
TWA	Time weighted average employee exposure over an eight hour work shift as defined in 29 CFR 1910.1000(d)(1).
$\bar{x}$	Estimated TWA employee exposure as calculated by a combination of long term or short term samples which represents (provides the best estimate of) the employee's actual exposure as averaged over an eight hour work shift.
σ	Standard deviation which is well known from prior data (can be estimated by s).
μ	True average of a population and is usually referred to as the mean to differentiate it from the calculated average of a group of samples drawn from the population
σ_ℓ	Standard deviation of ln (base e logarithms) which can be estimated by s_ℓ.

REFERENCES

1. Leidel, N.A. and K.A. Busch: Statistical Methods for the Determination of Noncompliance with Occupational Health Standards, NIOSH Technical Publication 75-159 (1975).

2. Roach, S.A.: Testing Compliance with ACGIH Threshold Limit Values for Respirable Dusts Evaluated by Count, Trans. ACGIH, 27-39 (1966).

3. Roach,S.A.: A More Rational Basis for Air Sampling Programs, AIHA J., 27, 1-12 (1966).

4. Roach, S.A., Baier, E.J., Ayer, H.E., and R.L. Harris: Testing Compliance with Threshold Limit Values for Respirable Dusts, AIHAJ, 27, 1-12 (1966).

5. Kerr, G.W.: Use of Statistical Methodology in Environmental Monitoring, AIHA J., 23, 75-82 (1962).

6. Larsen, R.I.: A Method for Determining Source Reduction Required to Meet Quality Standards, JAPCA, 11, 71 (1961).

7. Larsen, R.I.: A New Mathematical Model of Air Pollutant Concentration Averaging Time and Frequency, JAPCA, 19, 24 (1969).

8. Phinney, D.E. and J.E. Newman: The Precision Associated with the Sampling Frequencies of Total Particulate at Indianapolis, Indiana, JAPCA, 22, 692-695 (1972).

9. Larsen, R.I.: A Mathematical Model for Relating Air Quality Measurements to Air Quality Standards, AP-89, Environmental Protection Agency, U.S. Gov't Printing Office (1971).

10. Breslin, A.J., Ong, L., Glauberman, H., George, A.C., and P. LeClare: The Accuracy of Dust Exposure Estimates Obtained from Conventional Air Sampling, AIHA J, 28, 56-61 (1967).

11. Sherwood, R.J.; On the Interpretation of Air Sampling for Radioactive Particles, AIHAJ, 27, 98-109 (1966).

12. Sherwood, R.J.: The Monitoring of Benzene Exposure by Air Sampling, AIHA J, 32, 840-846 (1971).

13. Jones, A.R., and R.S. Brief: Evaluating Benzene Exposures, AIHA J, 32, 610-613, (1971).

14. Gale, H.J.: The Lognormal Distribution and Some Examples of Its Application in the Field of Radiation Protection, Atomic Energy Research Establishment Report AERE-R 4736, Her Majesty's Stationery Office (1965).

15. Gale, H.J.: Some Examples of the Application of the Lognormal Distribution in Radiation Protection, Ann. Occup. Hyg.., 10, 39-45 (1967).

16. Coenen, W.: The Confidence Limits for the Mean Values of Dust Concentration, Staub, 26, 39-45 (Engl. Translation) (May 1966).

17. Coenen, W.: Measurement Assessment of the Concentration of Health Impairing, Especially Silocogenic Dusts at Work Places of Surface Industries, Staub, 31, 16-23 (Engl. Translation)(December 1971).

18. Hounam, R.F.: An Application of the Log-Normal Distribution to Some Air Sampling Results and Recommendations on the Interpretation of Air Sampling Data, Atomic Energy Research Establishment Report AERE-M 1469, Her Majesty's Stationery Office (1965).

19. Juda, J., and K. Budzinski: Fehler bei der Bestimmung der mittleren Staubkonzentration als Funktion der Anzahl der Einzelmessungen, (Errors in Determining the Mean Dust Concentration as a Function of the Number of Individual Measurements), Staub, 24, 283-287, (August 1964).

20. Juda, J., and K. Budzinski: Determining the Tolerance Range of the Mean Value of Dust Concentration, Staub, 27, 12-16 (Engl. Translation).

21. LeClare, P.L., Breslin, A.J., and L. Ong: Factors Affecting the Accuracy of Average Dust Concentration Measurements, AIHA J, 30, 386-393 (1969).

22. Hald, A: Statistical Theory with Engineering Applications, John Wiley and Sons, New York (1952).

23. Ayer, H. and J. Burg: Time-Weighted Average vs. Maximum Personal Sample, paper presented at the AIHC, Boston, Mass. (1973).

24. Aitchinson, J. and J.A.C. Brown: The Lognormal Distribution, Cambridge at the University Press, Cambridge, England (1963).
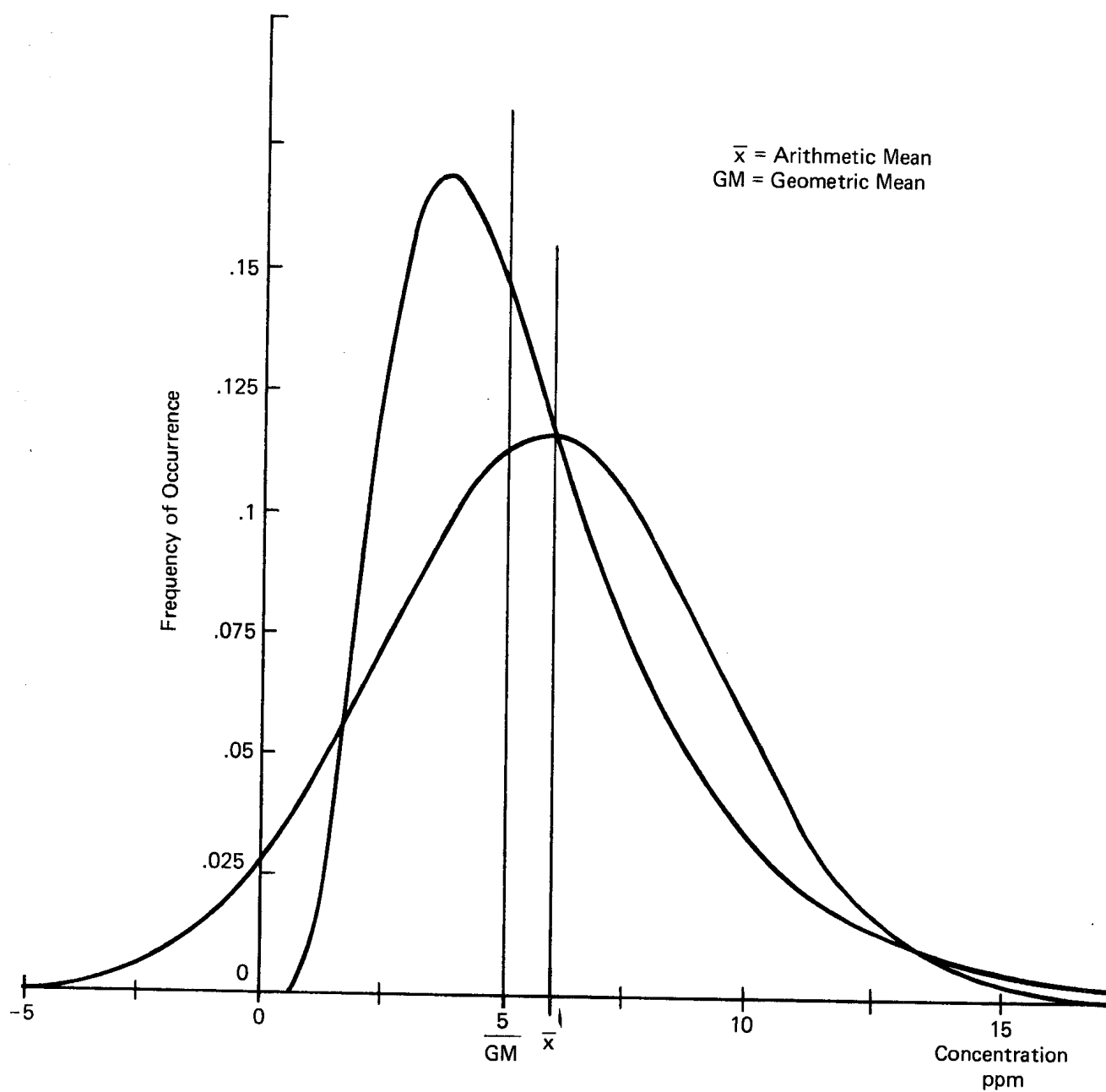
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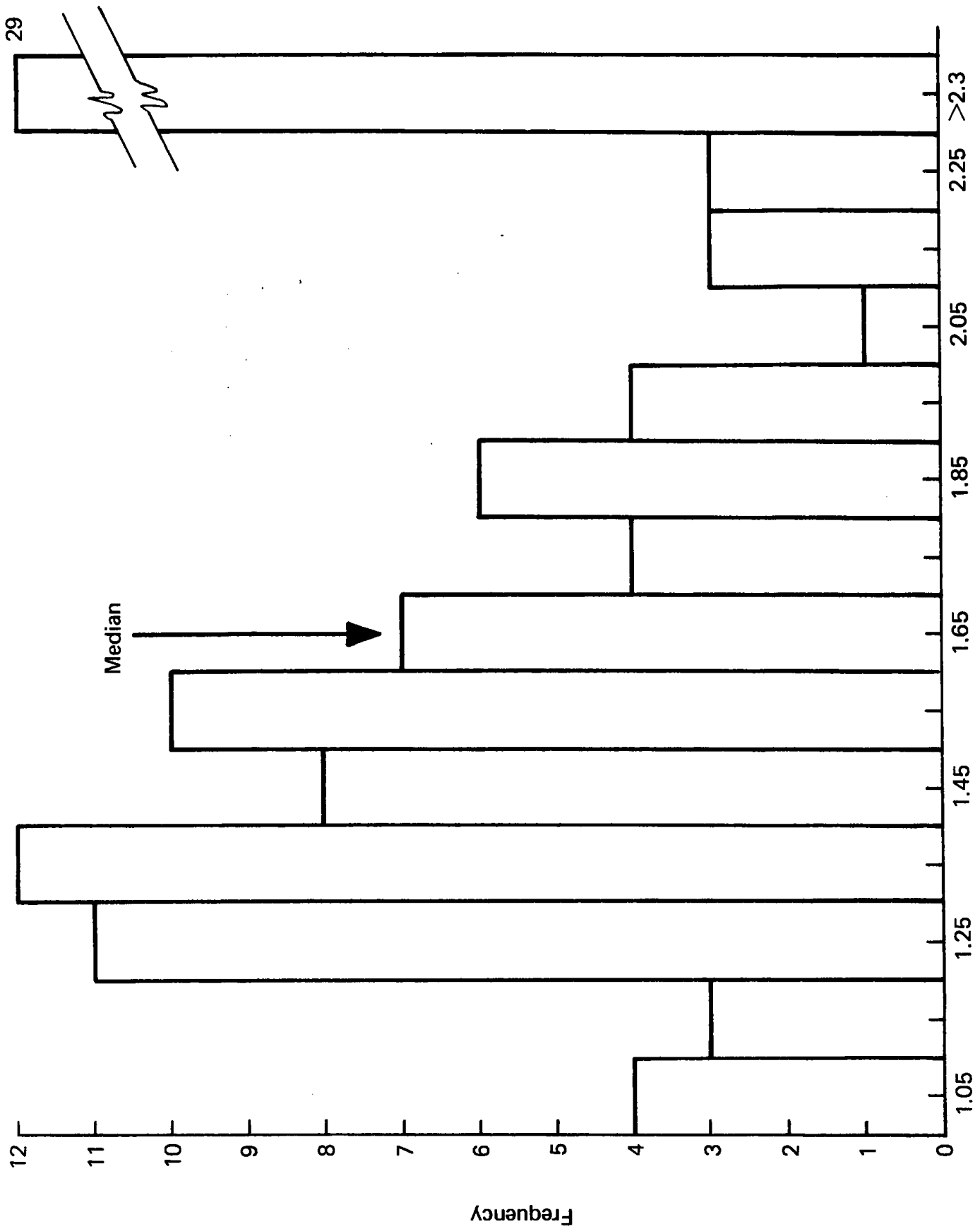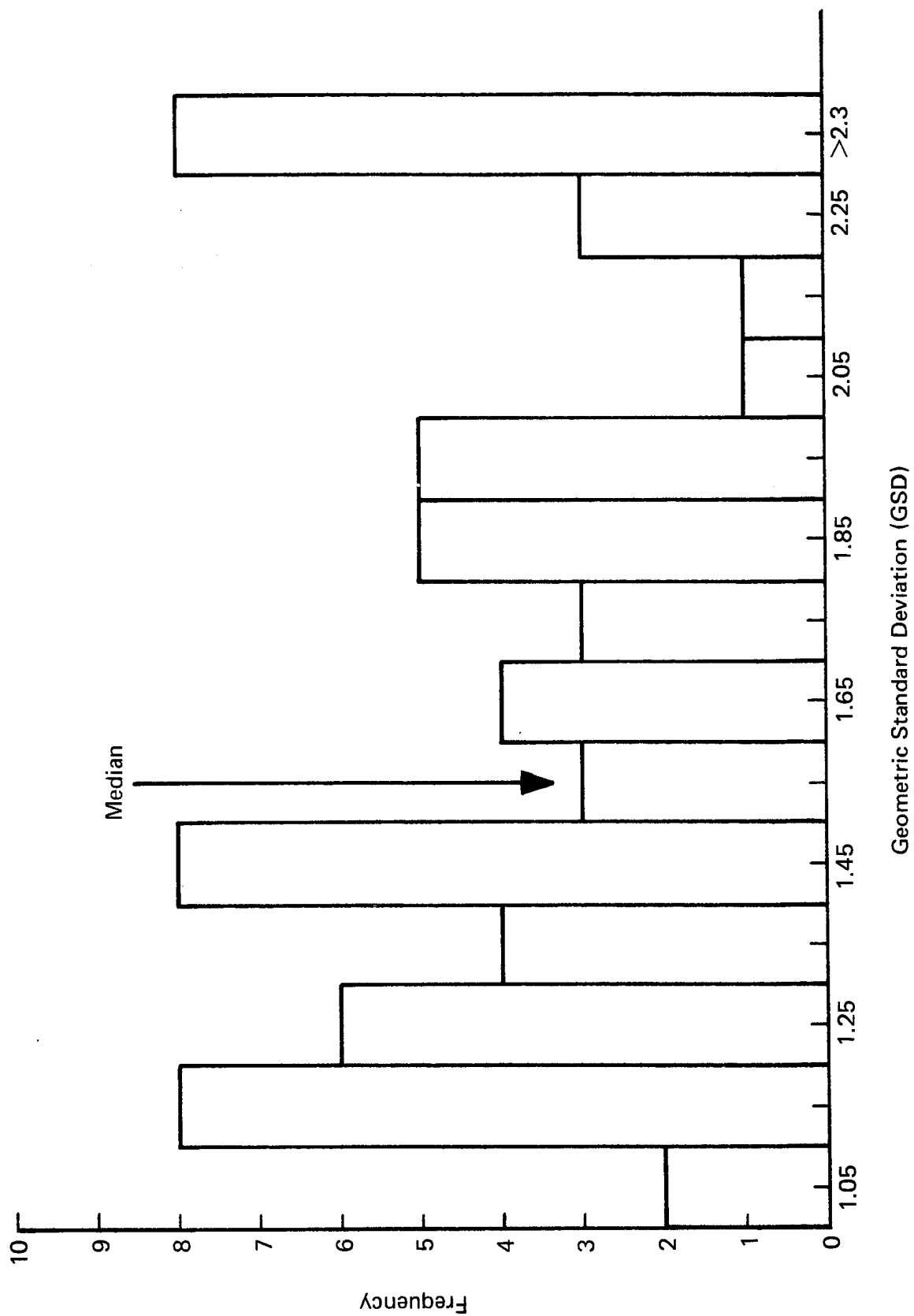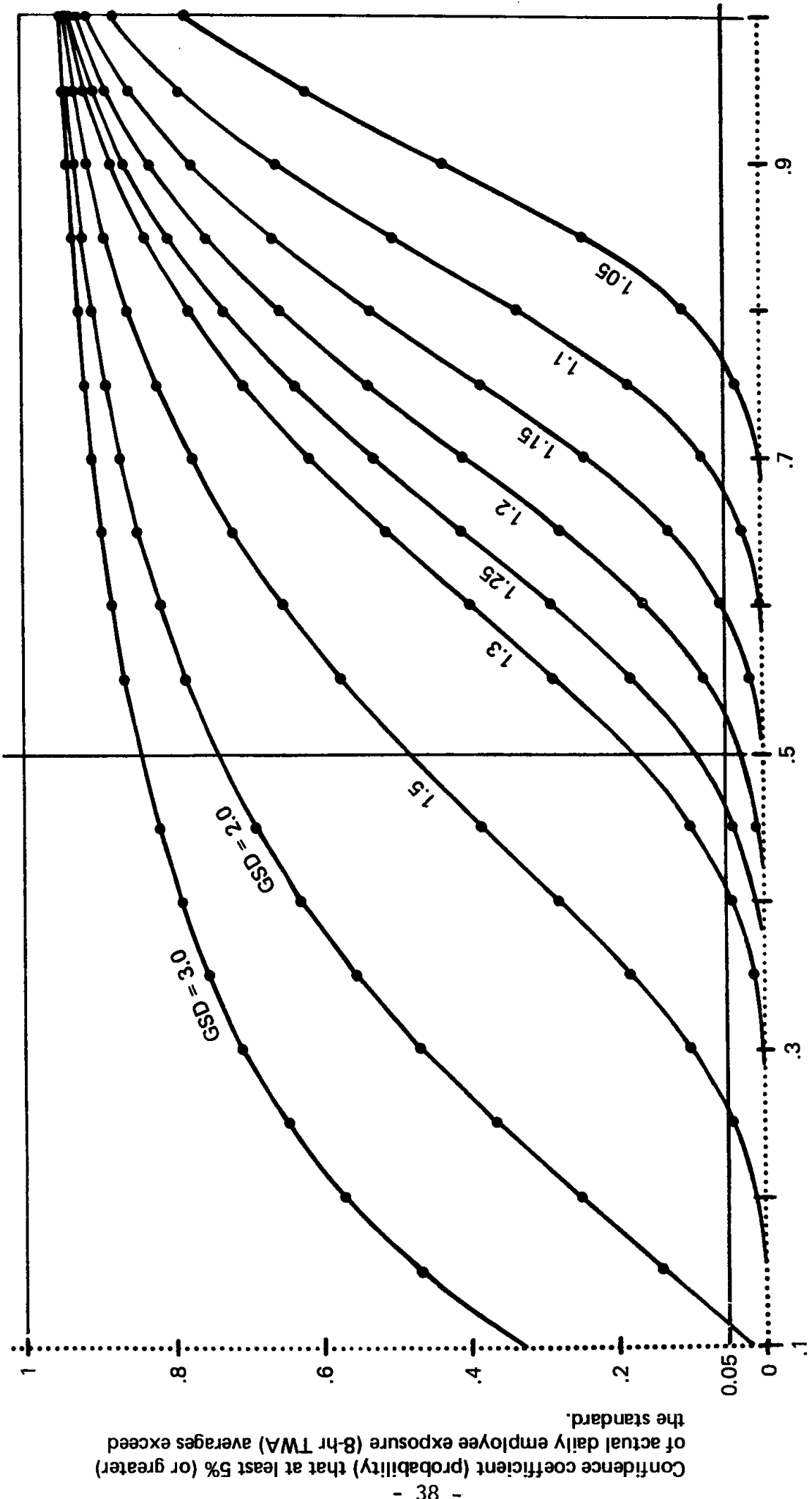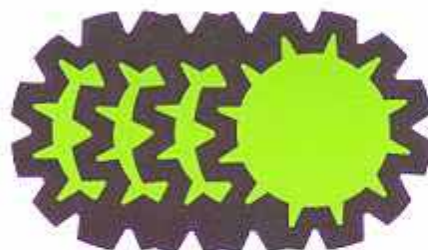
Figure 1

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Figure 2

Figure 3

Employee exposure 8-hr TWA measurement for one day as a fraction of the standard

Figure 4

Confidence coefficient (probability) that at least 5% (or greater) of actual daily employee exposure (8-hr TWA) averages exceed the standard.

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